

REMARKS

Claims 1-37, 45-47, 57-61 and 73-76 are pending.

Applicants thank the Examiner for discussing the pending claims in a telephone conference.

Present amendment cancels Claims 6,8,10,18,19 and 25 without prejudice, amends Claims 1,5,7,9,11,12,14,20-24,26-32 and 73, and adds new Claims 77 and 78.

Applicants point out that all claims in the present amendment now also provide that the pharmaceutical composition:

contains eplerenone in a D₉₀ particle size of about 25 to about 400 microns,

about 0.5 to about 30 weight percent of one or more disintegrants,

about 5 to about 99 weight percent of one or more diluents,

about 0.5 to about 25 weight percent of one or more binding agents,

wherein at least about 80% of the eplerenone is dissolved in vitro within about 30 minutes in 0.1N HCl at 37°C.

Claim amendments find support in the specification at page 7, lines 21 to 30; page 27, lines 10 to 19; and page 33, lines 4 to 14. New Claims 77 and 78 and the amendment to disintegration time in amended Claim 1 find support at page 33, lines 16 to 22.

Applicants reserve the right to file continuation applications with claims directed to the subject matter of now-canceled Claims 6,8,10,18,19 and 25.

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Rejection Under 35 USC §103(a)

Independent, presently amended Claim 1 (to a pharmaceutical composition) and Claim 57 (to a method of using the pharmaceutical composition of Claim 1) both now require that the pharmaceutical composition comprises:

- (1) Particulate eplerenone having a D_{90} particle size of about 25 to about 400 microns,
- (2) in an amount from about 25 mg to about 100 mg,
- (3) about 0.5 to about 30 weight percent of one or more disintegrants,
- (4) about 5 to about 99 weight percent of one or more diluents,
- (5) about 0.5 to about 25 weight percent of one or more binding agents,
- (6) wherein the composition is an immediate release composition,
- (7) wherein at least about 80% of the eplerenone is dissolved in vitro within about 30 minutes in 0.1N HCl at 37°C, and
- (8) wherein the composition substantially disintegrates within about 30 minutes when placed in a water bath maintained at a temperature of 37°C \pm 2°C.

Pending Claims 1-37, 45-47, 57-61 and 73-76 were rejected under 35 USC §103(a), as being unpatentable over Grob, et al., U.S. Patent No. 4,559,332 ("Grob"), in view Remington (1995): The Science and Practice of Pharmacy, vol. 2 ("Remington").

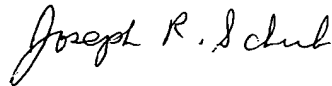
In view of the claim amendments submitted herein, a *prima facie* conclusion of obviousness over Grob, in view of Remington, has not been established. For example, none of these references, either alone or combined, teaches or even suggests all the claim limitations in the amended claims (MPEP § 2143).

Withdrawal of the rejection under 35 USC §103(a), as being unpatentable over Grob, in view of Remington is therefore respectfully requested.

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Favorable consideration and early allowance of pending claims is requested. Applicants respectfully request a three-month extension of time to and including January 1, 2006 for filing a response to the July 1, 2005 Office Action in this matter. The Commissioner is hereby authorized to charge the \$1020.00 fee for the requested three-month extension of time under 37 C.F.R. 1.17, together with any fees that may be required during the entire pendency of this application, to Deposit Account No. 19-1025.

Respectfully submitted,



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